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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,871	10/20/2000	Alexandre Marti	NITROS P146US	6986
20210	7590	10/06/2004		
DAVIS & BUJOLD, P.L.L.C. FOURTH FLOOR 500 N. COMMERCIAL STREET MANCHESTER, NH 03101-1151			EXAMINER SHARAREH, SHAHNAM J	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/673,871	Applicant(s) MARTI ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27, 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Pursuant to the Grant of the Petition to Revive, issued on August 18, 2004, Examination on the merits of this Application resumes. Amendment filed January 16, 2004 has been entered. Claims 19-27, 29-35 are pending.

Examiner requests that all future filings bare the Serial Number 09/673,871 to avoid any confusion. Any rejection that is not addressed in this Office Action is considered obviated in view of the claim amendments and the presented arguments.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19-27, 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giersckky et al US Patent 6,034,267.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Applicant first argues that Giersckky disclosure is the same as a previously cited prior art WO96/28412 ("WO '412"), and thus Giersckky cannot render the present claims obvious, because the previous rejection over WO '412 was withdrawn in the last Office Action. (Arguments at page 7, 4th para). This line of argument is not persuasive, because claims were presented with new limitations.

In response, Examiner states that throughout the prosecution of an application, claims are examined with as they are presented. In this case, following the Afterfinal Amendment filed on March 17, 2003, Examiner did not deem the rejections of record at

that time to be applicable because of the newly added limitations. Therefore, a new rejection was made to address the presented limitations at the time.

Applicant then argues that there is no motivation to modify Gierskcky to modify the reference to arrive at the claimed invention. (Arguments at page 7, 5th para.).

In response Examiner states that contrary to Applicant's reasoning modification of proportions and ranges is not patentable, as a matter of law, unless there is a showing of criticality. See *In re Becket*, 33 USPQ, 33 (CCPA 1937). *In re Russell*, 439 F.2nd 1228, 169 U.S.P.Q. 426 (CCPA 1971): Applicant has not met the burden of showing that the instantly claimed ranges are critical to operation of preparing a solution that contains an ester of 5-ALA. Thus, the rejection is maintained for the reasons of record.

Gierskcky et al teaches pharmaceutical compositions for treating or diagnosing a condition comprising an ester of ALA. (see col 3, lines 1-30). Gierskcky teaches the concentrations of the compounds in Gierskcky's compositions are generally about 1 to 50% (see except the instantly claimed ranges of ALA esters. (col 6, lines 24-33). Gierskcky also teaches the use of chelating agent such as deferroxamine or alike in his compositions (see col 7, lines 21-33). Gierskcky teaches methods of preparing and using ALA hexyl ester (see example 4, and 15). All elements of the instant claims are described in Gierskcky, except the instantly claimed ranges ester of ALA. But as the matter of law, absence of showing a criticality, it would have been *prima facie* obvious to optimize the concentration of Gierskcky's ALA-esters and their respective pH ranges to achieve a desirable clinical outcome.

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Applicant also adds that no knowledge generally available to one of ordinary skill in the art to arrive at the claimed concentrations of ALA-ester doses lower than 1%. (see Arguments at page 7, 5th para.). However, Examiner states that contrary to such statement applicant's declaration contains articles by Lang et al, Qian Peng et al and Marti et al that esterified aminolevulinic acid derivatives induces porphyrin fluorescence in skin. Such teachings were available to one of ordinary skill in the art because the artisans before filing of the instant Application knew them. Accordingly, optimizing the concentrations of a formulation to achieve such end-result would have been within the skill of the ordinary level in the art and available at the time of claimed invention. (see Applicant's Declaration filed on January 16, 2004, paragraph 12-14).

Further, the Declaration under 37 CFR 1.132 filed January 16, 2004 is insufficient to overcome the rejection of claim 19-27, 29-35 based upon Giersckky as set forth in the last Office action because: it is not commensurate with the scope of the claims and does not provide adequate data comparing the formulations of Griersckky to establish unexpected or criticality of lower ranges ALA esters of the claimed invention.

As the initial matter the opinion declaration explains methods of using esters of ALA at a lower concentrations as conventionally employed in the art at the time of publication of the cited references. Such studies did not describe unexpected observations in formulating lower concentrations of esterified ALA. Therefore, Applicant's arguments that preparing a formulation of esterified 5-ALA is not commensurate with the scope of the claims, because the instant claims are not directed to methods of using such compositions.

Second, Applicant has not provided any comparative data between esterified formulations of Griessky and the instant claims. Griessky even teaches esterified ALA compositions at concentrations 1% by weight or lower (see examples 1-5). However, no data are submitted in the Declaration that the instantly claimed formulations provide unexpected results over Griessky or the concentrations of esterified ALA in the instant compositions are critical for preparing the claimed compositions.

Examiner also adds that there is long legal precedent that [O]bviousness does not require absolute predictability of success. *In re Merck & Co.*, 800 F.2d at 1098, 231 USPQ at 380; *In re Papesch*, 315 F.2d 381, 386-87, 137 USPQ 43, 47-48 (CCPA 1963). For obviousness under §103, all that is required is a reasonable expectation of success. *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). It is Examiner's position that the information in the Griessky reference provides such a reasonable expectation of success. Applicant has not provided adequate support to show nonobviousness. Therefore, the rejection is maintained.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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